[OPTS-42078; TSH-FRL #2904-1]

Sodium N-Methyl-N-Oleoyltaurine; Decision Not To Test

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice is EPA's response to the Interagency Testing Committee's (ITC) recommendation that EPA consider requiring health-effects testing of sodium *N*-methyl-*N*-oleoyltaurine (SMOT, CAS No. 137-20-2) under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not initiating a rulemaking at this time under section 4(a) of TSCA to require health or environmental effects testing of SMOT. EPA's analysis of available data indicates that few people are exposed to this chemical, exposure levels are low, and only small amounts of this chemical are released to the environment. Existing information on health effects does not suggest potential for an unreasonable risk at expected exposure levels.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll Free:

(800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is not initiating a rulemaking under section 4(a) of TSCA to require testing of SMOT for the reasons presented below.

I. Background

A. ITC Recommendation

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established the ITC to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated SMOT for priority consideration in its 15th Report, published in the Federal Register of November 29, 1984 (49 FR 46931). This notice constitutes EPA's response to the ITC designation of SMOT. The ITC recommended that SMOT be considered for a staged health effects testing program consisting of short-term genotoxicity, sensitization in appropriate test systems, and chronic toxicity/oncogenicity (conditional upon the results of the short-term tests). The basis of these recommendations was as follows: production of 300,000 to 3.1 million pounds per year, potential for worker exposure in the textile and pesticide formulation industries, and potential for consumer exposure via the compound's use in products such as household detergents, rug shampoos, laundry soaps and surface coatings. The ITC concluded that there was a lack of sufficient data to characterize the effects of concern for SMOT. No environmental effects tests were recommended by the ITC because several studies of SMOT or SMOT analogs indicated rapid degradation, including one in which SMOT was found to be degraded by 75 percent in Chesapeake Bay water within 1-4 days (Ref. 1).

B. Regulatory Development

Under section 4(a)(1) of TSCA, EPA shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure, and release information to determine whether there is or may be substantial production and significant or substantial human exposure or substantial release to the environment. For the findings under sections 4(a)(1)(A)(ii) and (B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of, human exposure to, or environmental release of, the chemical. In making the finding under section 4(a)(1)(A)(iii) or (B)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed at 46 FR 30300 and 48524 and the section 4(a)(1)(B) findings are discussed at 46 FR 30300.

In evaluating the ITC's testing recommendations for SMOT, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of SMOT under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716) on SMOT; published and unpublished data available to the Agency.

II. Review of Available Data

A. Physical Characteristics

SMOT (CAS No. 137-20-2) is an anionic surfactant produced in the form of a fine white powder with a sweet odor (Ref. 2). Its estimated melting point is 76.5°C, estimated boiling point is 387°C, estimated vapor pressure is 14.45×10^{-5} mm Hg, estimated solubility in water is 9.2 mg/L, calculated log K(OW) is 4.29, and calculated log K(OC) is 4.08 (Ref. 3).

B. Production

An industry estimate of 1983 production of SMOT is approximately 1.2 million pounds (Ref. 4), while the U.S. International Trade Commission (USITC) reported the 1983 production volume for a group of taurine-derived anionic surfactants to be 2.277 million pounds (Ref. 5). The taurine derivatives included were SMOT; *N*-(coconut oil acyl)-*N*-methyltaurine, sodium salt; *N*-cyclohexyl-*N*-palmitoyltaurine, sodium salt; *N*-methyl-*N*-palmitoyltaurine, sodium salt; and *N*-methyl-*N*-(tall oil acyl)taurine, sodium salt. Sales of SMOT have remained steady for the past 4 years (Ref. 6). SMOT is produced by six firms: Crown-Metro, Inc., GAF Corp., Hart Products Corp., Finetex, Inc., Griffex Chemicals, and CNC Chemical Corp. American Hoechst, Inc., imports SMOT. U.S. production is conducted at six sites by batch processes (Ref. 7). The largest producer is GAF Corp. (Ref. 8).

C. Human Exposure

Four of the six producers that responded to queries about production reported very similar methods (Refs. 9 through 12). It is likely, therefore, that production methods are consistent throughout the industry. The following production details were supplied by the largest manufacturer (well over 50 percent of U.S. production) (Refs. 8 and 9.)

SMOT is manufactured on a batch basis. Batches are produced for approximately 3 weeks, which is defined as a campaign. Ten to twelve campaigns are run each year. The starting materials are charged into a reactor and allowed to react. When reaction is complete the aqueous product is discharged. The process is designed and operated so that there is no intentional release of the product. The substance is handled in solution; therefore, fugitive releases are unlikely. A total of 6 workers at one

plant are involved in the manufacture of the solution. Because of the physical form, worker exposure is limited to inadvertent releases such as spills or splashes, and therefore chemical gloves, protective aprons, and chemical goggles are considered sufficient.
Approximately 10 percent of the product is sold in this form. An additional 10 percent is further diluted with water or water/alcohol for the slurry and gel forms.

The solid form is produced by the drum drying of the solution. Nine workers are potentially exposed during this phase. This step in the processing results in the evolution of steam which is controlled and released to the environment. The material is then bagged or drummed in an enclosed process. Although the product is capable of minor dusting, losses in this phase of manufacturing, including workplace and environmental release, account for only 500 lbs. per year (Ref. 9).

Although the above description concerns only one SMOT manufacturer, confidential information submitted by the other manufacturers leads the Agency to conclude that manufacturing worker exposure to SMOT is not substantial.

The major users of SMOT are the textile and pesticide-formulating industries (Ref. 8). In textile mills many different surfactants including SMOT are used for the washing of fabrics before dyeing, during the dyeing per se, and for washing after dyeing (Ref. 13). Only the liquid form of SMOT is used in textile mills (Ref. 14). One worker on each of the three shifts dilutes the 32-percent SMOT (concentration received from manufacturer) to 1–2 percent before mixing it with the wash water or dye bath. The resulting concentration in the baths is approximately 0.07 percent (Ref. 14). Protective clothing is available for these workers, but the extent to which it is used varies from mill to mill. At times workers are required to cut swatches from the damp fabric to check the color. Although they wear gloves for this operation, they may remove them in the process of rinsing the swatch and thereby come in contact with SMOT (Ref. 13). According to the National Occupational Hazard Survey conducted by the National Institute for Occupational Safety and Health (1972–1974), approximately 585 textile workers are potentially exposed to SMOT (Ref. 15).

A minor application of SMOT is in the production of black and white photographic paper. Worker exposure for this entire industry has not been determined. However, EPA believes the exposure to be very slight because of the high degree of automation of the process and the need for enclosure of the process because of light sensitivity. In the production process of one of the largest producers of this type of photographic paper, 11 employees are potentially exposed during the process of mixing chemicals. Each one is exposed approximately 9 times per year for about 3 minutes per exposure or 27 minutes of exposure per worker per year. This is equivalent to 5 worker hours per year (Refs. 16 and 25).

The only confirmed TSCA use of SMOT in a consumer product is black and white photographic paper in which SMOT is encapsulated in the coating at a concentration of less than 0.01 percent. This paper is developed by the wet process (Refs. 17 and 18).

Although the ITC believed SMOT was used as a component of rug shampoos, laundry soaps, household detergents, and surface coatings (49 FR 46931), EPA could find no evidence of these uses.

Pesticide formulators use the dry or flake form of SMOT which consists of at least 67 percent SMOT, 19–20 percent sodium chloride, 8–9 percent sodium oleate, 1–3 percent water, and a trace of sodium sulfate (Ref. 9). The particles are approximately 0.5 to 1 mm in diameter; therefore, dusting and worker inhalation are minimal (Ref. 19). There are approximately 20 sites with six workers per site in the U.S. where pesticide-formulating workers could be potentially exposed to SMOT (Ref. 20).

D. Health Effects

1. *Acute oral toxicity.* Seidenfaden (Ref. 21) reported that the oral LD_{50} of SMOT in mice was 3.7 g/kg body weight.

Hopper et al. (Ref. 22) found the oral LD_{50} in Harlan strain albino mice to be 6.63 g/kg body weight. The mice (10/group) received 0.5 cc of solution/20 g body weight. All deaths occurring within 72 hours of treatment were considered compound related. Hopper et al. (Ref. 22) also determined that the intravenous LD_{50} value for SMOT in mice is 0.35 g/kg. Animals were observed for 24 hours after treatment in this case.

Other acute oral toxicity studies for SMOT with similar results are included in Ref. 9.

2. *Primary dermal irritation.* In a study of dermal irritation, six New Zealand white rabbits of mixed sex were employed. One-half milliliter of a 20-percent aqueous solution of Tauranol MS® (the paste form of SMOT produced by Finetex, 32 to 33 percent active ingredient) adjusted to pH 7.0 was applied to clipped areas of intact and abraded skin. The test material was covered by an occlusive patch which was removed after 24 hours. The application sites were observed and scored for erythema and edema 24 and 72 hours following treatment. The primary irritation index calculated from these scores was 0.60, which was interpreted to mean that the potential exists from this compound to be slightly irritating (Ref. 23).

Another acute dermal irritation animal study for SMOT with similar results is included in Ref. 21.

In an epicutaneous test, SMOT was applied to the skin of highly eczematic persons as an aqueous solution and left to dry (Ref. 21). SMOT was reported to have very good skin compatibility. No further details were provided.

3. *Primary eye irritation.* In a study of ocular irritation in six New Zealand white rabbits, a 20-percent aqueous solution of Tauranol MS® (pH 7.0) was employed (Ref. 23). One-tenth milliliter was applied to the right eye of each animal. The untreated left eye served as a control. The treated eyes remained unwashed for hours. The eyes were observed 1, 2, and 3 days after treatment and were scored for the presence and severity of ocular lesions. The total possible score/animal/day was 110. On day 1, the average score for six animals was 3.0. On days 2 and 3, the score for all animals was 0.0. The authors concluded that SMOT was not an ocular irritant to rabbits under these conditions.

Other acute ocular irritation studies for SMOT with similar results are included in Refs. 9, 21 and 22.

4. *Primary dermal sensitivity.* An *in vivo* study to determine photoallergic and contact allergic potentials of Igepon TC-42® (at least 24 percent SMOT, 8 percent sodium chloride, 65 percent water and a trace of sodium sulfate) on human skin was conducted with 31 human females age 20 to 63. The test material was diluted with water to 50 percent and applied on the inner aspect of the forearm. The other forearm was considered the control. Patches remained in place for 24 hrs. after which the degree of dermal response was recorded. Selected contact sites were then subjected to ultraviolet irradiation 3 days per week for 10 irradiations. After a 10 to 13 day rest, challenge patches were applied to virgin adjacent sites. After 24 hrs, test sites were examined for degree of response. Virgin sites were then irradiated and readings taken 24 and 48 hrs later. Only transient reaction was observed; the test was considered to be negative (Ref. 9).

Another dermal sensitization test for SMOT with human volunteers with similar results is included in Ref. 9.

5. *Subchronic oral toxicity.* Five or 10 mice receiving 10 percent of the SMOT LD_{50} by gavage (or 663 mg/kg body weight) daily, 6 days/weeks for a total of 25 doses, were dead by the tenth dose (Ref. 22). The rest of the animals survived to the end of the experiment. No further details were provided.

Fitzhugh and Nelson (Ref. 24) conducted a 16-week experiment in which SMOT was fed to groups of five male weanling Osborne-Mendel rats as 0.5, 1, 2, 4, and 8 percent of the diet. Body weights and food consumption were determined at weekly intervals. An apparent dose-related decrease in growth was seen over the 16-week period. At dosage levels of 4 and 8 percent, retardation of the growth rate reached significant levels ($p<0.05$). Two of the five animals receiving the 8-percent concentration died with gastrointestinal irritation during the experimental period. Gross examination of animals sacrificed at 16 weeks showed concentration-dependent gastrointestinal irritation, which probably prevented proper nutritional intake at the higher doses. No microscopic examinations were performed.

Repeated feeding of SMOT (100 mg/kg body weight) to male albino rats (mixed strains) did not produce any apparent effects (Ref. 20). The available report does not specifically state whether SMOT was administered by gavage or incorporated into the diet. The study was described as subchronic, but its duration was not reported. Blood and urine samples were analyzed, and macroscopic and histological examinations were performed upon autopsy without revealing any detrimental effects. No further details were reported.

The Agency believes that these subchronic test data do not suggest that human exposure to SMOT may present an unreasonable risk to human health.

6. *Teratogenicity and reproductive toxicity.* The Agency has no data on the teratogenicity and reproductive toxicity of SMOT.

7. *Mutagenicity.* The Agency has no data on the mutagenicity of SMOT.

8. *Carcinogenicity. The Agency has no data on the carcinogencity of SMOT.*

III. Decision Not to Initiate Rulemaking

EPA has decided not to initiate rulemaking to require health effects testing of SMOT under section 4 of TSCA. The basis for this determination is that because of its limited potential for human exposure there is not significant or substantial human exposure nor do existing data provide any reason for believing that SMOT may present an unreasonable risk of injury to human health.

Human exposure to SMOT is expected to be minimal for the following reasons:

(a) Very few SMOT production workers are potentially exposed. The process is essentially closed, and, except for the drying process, SMOT is in solution. Owing to its low vapor pressure, there is little prospect for worker exposure via inhalation. During the drying operation, a small number of workers could be potentially exposed to 150 mg/day (OSHA nuisance dust limit).

(b) Three industries use SMOT: textile production, pesticide formulation, and black and white photographic paper production. Relatively few workers are exposed in these industries, and the majority of these workers are exposed to very low SMOT concentrations.

(c) The potential for consumer exposure is very slight. The only known consumer product containing SMOT is photographic paper. The SMOT, present below 0.01 percent, is expected to remain encapsulated in the coating on the paper.

Acute and subchronic oral toxicity testing of SMOT indicate a low degree of toxicity. Oral subchronic effects are apparently due to gastrointestinal irritation; no organ-specific effects were recorded. Only mild irritation was elicited by acute dermal and ocular tests. Skin sensitization testing produced negative results. The Agency has no data indicating reproductive toxicity, mutagenicity, or carcinogenicity for SMOT.

The available toxicity data on SMOT (discussed in Unit II.D.) do not provide any basis to believe that these levels of exposure to SMOT may present an unreasonable risk of health effects to the exposed workers or consumers.

IV. Public Record

EPA has established a public record for this decision not to test under section 4 of TSCA (docket number OPTS-42078). The record includes the following information:

A. Support Documentation

(1) **Federal Register** notices pertaining to this decision consisting of:

(a) Notice containing the ITC designation of SMOT to the Priority List.

(b) Notices requiring TSCA section 8(a) and (d) reporting for SMOT.

(2) Communications consisting of:

(a) Written public and intra-agency or interagency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Summaries of meetings.

(d) Reports—published and unpublished factual materials, including contractors' reports.

References

(1) Cook T.M., Goldman C.K. "Degradation of anionic detergents in Chesapeake Bay." *Chesapeake Science*. 15(1):52-55. 1974.

(2) Hawley, G.G. The Condensed Chemical Dictionary. 9th ed. New York, NY: Van Nostrand Reinhold Co., p. 795. 1977.

(3) USEPA. U.S. Environmental Protection Agency, Washington, D.C. Interoffice memorandum from P. Harrigan, Design and Development Branch, to R. Sanford, Test Rules Development Branch. July 26, 1985.

(4) Huse, G. Crown-Metro Corp., P.O. Box 5695, Echelon Rd., Donaldson Center, Greenville, SC 29606. Summarized telephone conversation with R.B. Sanford, U.S. Environmental Protection Agency, Washington, D.C. April 17, 1985.

(5) USITC. U.S. Internatl. Trade Commission. Synthetic organic chemicals. United States production and sales, 1983. Publication No. 1588. Washington, D.C.: U.S. Government Printing Office. 1984.

(6) Ansell, J. GAF Corp., 1361 Alps, Wayne, NJ 07470. Summarized telephone conversation with R. Sanford, U.S. Environmental Protection Agency, Washington, D.C. June 14, 1985.

(7) Syracuse Research Corp., Merrill, La., Syracuse, NY 13210. Letter from M. Neal to R. Sanford, U.S. Environmental Protection Agency, Washington, D.C. October 1, 1965.

(8) Ansell, J. GAF Corp., 1361 Alps, Wayne, NJ 07470. Summarized telephone conversation with R. Sanford, U.S. Environmental Protection Agency, Washington, D.C. June 3, 1985.

(9) GAF Corp. "GAF Response to EPA, Sodium N-Methyl-N-Oleoyltaurine OPTS-41015; FRL-2725-F" June 1985.

(10) Crown Metro, Inc. Greenville, SC 29606. Letter from G.C. Huse to M. Neal, Syracuse Research Corp., Syracuse, NY 13210. February 8, 1985.

(11) Grifftex Chemicals. Opelika, AL 36801. Letter from D.A. MacEwen to M. Neal, Syracuse Research Corp., Syracuse, NY 13210. February 5, 1985.

(12) C.N.C. Chemical Corp. Technical bulletin: GEL CONC: manufacturing process. P.O. Box 997, Annex Station, Providence, RI 02901. n.d.

(13) USEPA. U.S. Environmental Protection Agency, Washington, D.C. Summarized interoffice telephone conversation between G. Heath, Chemical Engineering Branch and R. Sanford, Test Rules Development Branch. August 5, 1985.

(14) MacEwen, D. Grifftex Chemicals/Westpoint-Pepperilli, Inc., 1900 Cunningham Dr., Opelika, AL 36801. Summarized telephone conversation with R. Sanford, U.S. Environmental Protection Agency, Washington, D.C. August 2, 1985.

(15) Sunden, D. National Institute for Occupational Safety and Health, Cincinnati, OH. Summarized telephone conversation with R. Sanford, U.S. Environmental Protection Agency, Washington, DC. July 31, 1985.

(16) Humphreys, J. Eastman Kodak Co., Rochester, NY 14650. Summarized telephone conversation with S. Beals, Syracuse Research Corp., Merrill, La., Syracuse, NY 13210 August 12, 1985.
(17) Eastman Kodak Co. Rochester, NY 14650. Letter from R.L. Raleigh to M. Neal, Syracuse Research Corp., Syracuse, NY 13210. May 17, 1985.
(18) Neal, M. Syracuse Research Corp., Morrill, La., Syracuse, NY 13210. Summarized telephone conversation with R. Sanford, U.S. Environmental Protection Agency, Washington, D.C. August 5, 1985.
(19) Ansell, J. GAF Corp., 1361 Alps, Wayne, NJ 07470. Summarized telephone conversation with R. Sanford, U.S. Environmental Protection Agency, Washington, D.C. July 2, 1985.
(20) USEPA. U.S. Environmental Protection Agency, Washington, D.C. Interoffice memorandum between P. Quillen, Chemical Engineering Branch and R. Sanford, Test Rules Development Branch. August 14, 1985.
(21) Seidenfaden, M.L. "The use of taurides, sarcosides and isethionates in cosmetics." *American Perfumer and Cosmetics*, 81: 29–32. 1966.
(22) Hopper S.S., Hulpieu H.R., Cole V.V. "Some toxicological properties of surface-active agents." *Journal of American Pharmaceutical Association*, 38: 428–432. 1949.
(23) Finetex, Inc. Elmwood Park, NJ 07407. Final Report on the primary dermal irritation, ocular irritation and actue oral toxicity of Tauranol MS. Prepared by Consumer Product Testing Co., Inc., Fairfield, NJ 07006. 1978.
(24) Fitzhugh, O.G., Nelson, A.A. "Chronic oral toxicities or surface-active agents." *Journal of the American Pharmaceutical Association Science Edition*, 37: 29–32. 1948.
(25) Humphreys, J. Eastman Kodak Co. Rochester, NY 14650. Summarized telephone conversation with S. Beals, Syracuse Research Corp. Merrill, La., Syracuse, NY 13210. April 23, 1985.

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Rm. E-107, 401 M St., SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

(15 U.S.C. 2603)

Dated: October. 31, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 85-26528 Filed 11-5-85; 8:45 am]

BILLING CODE 6560-50-M